CLINICAL EDIT CRITERIA PROPOSAL

Drug/Drug Class: **HMG-Co A reductase inhibitors (statins)**

Prepared by: Missouri Medicaid

☐ **New Criteria** ☒ **Revision of Existing Criteria**

Executive Summary

Purpose: Reduce drug costs by limiting prescribing to one preferred (statins) drug, lovastatin

Why was Issue Selected: For the previous reporting period (July 2001 - June 2002), Missouri Medicaid Pharmacy Program paid $25,805,400 for HMG-Co A reductase inhibitors (statins) This represents 33.3% of the total drug spend.

Program Specific Information:	**Total Scripts in Drug Class**	**Projected Savings in Drug Class**
	304, 300	$7.7 million

Reference Drug/Drugs With No Clinical Edit Imposed:

Trade Name	**Generic Name**
MEVACOR	LOVASTATIN
ALTOCOR	EXTENDED RELEASE LOVASTATIN

Drugs, Which Will Be Affected By Clinical Edits:

Trade Name	**Generic Name**
LIPITOR	ATORVASTATIN
LESCOL	FLUVASTATIN
ADVICOR	NIACIN-LOVASTATIN
PRAVACHOL	PRAVASTATIN
ZOCOR	SIMVASTATIN

Setting & Population: All patients receiving an HMG-Co A reductase inhibitor other than lovastatin.

Type of Criteria: ☐ Increased risk of ADE ☐ Non-Preferred Agent ☐ Appropriate Indications

Purpose of Clinical Edit Criteria

While prescription expenditures are increasing at double-digit rates, payors are also evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. Clinical Edit criteria assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Clinical Edit criteria can also reduce the risk of adverse events associated with medications by identifying patients at increased risk due to diseases or medical conditions, or those in need of dosing modifications.

Why Has This Issue Been Selected For Review?

HMG-Co A reductase inhibitors (statins), are clearly effective agents in lowering LDL, increasing HDL, and decreasing triglycerides, and are appropriate first line agents in treating hypercholesterolemia.[1]

Drug Type	Effects
Statins	LDL ↓ 18- 55 % HDL ↑ 5-15 % TG ↓ 7-30 %
Bile Acid Sequestrants	LDL ↓ 15 -30 % HDL ↑ 3-5 % TG 0 change or ↓
Nicotinic Acid	LDL ↓ 5 -25 % HDL ↑ 15-35 % TG ↓ 20-50 %
Fibric Acids	LDL ↓ 5 -20 % HDL ↑ 10-20 % TG ↓ 20-50 %

Statins have been shown to reduce the incidence of major coronary events; coronary procedures, coronary heart disease deaths and stroke.[2] Major side effects of statins include myopathy and increased liver enzymes (dose dependent). When used with appropriate caution in certain high-risk patients, incidence of myopathy and elevated liver enzymes should be reduced.[2]
Of the statins, lovastatin is the most cost effective agent for the Pharmacy Program. Its side effect profile, as well as available medical and clinical information, are comparable to that of other statins. This product is a reference drug in national guideline approved therapy, and is consistent with consumer and medical recommendation sources.

Override Approval Criteria

Reference Drug Product: Lovastatin

- drug class for review: HMG-Co A reductase inhibitors (statins)
- documented ADE to lovastatin
- documented failure on lovastatin therapy

Override Denial Criteria

- no initial trial on reference drug(s)
- lack of adequate compliance during trial period

Required Documentation

- MedWatch Form
- Progress Notes

References

1. National Institute of Health 3rd Report. High Blood Cholesterol in Adults, Executive Summary. National Cholesterol Education Program. May 2001.
2. Journal of the American College of Cardiology. Clinical Advisory on the Use and Safety of Statins. Vol. 40, No 3, 2002.
3. Facts and Comparisons, 2002.
4. Micromedex Online. http://healthcare.micromedex.com/mdx
5. The Medical Letter, Inc. Choice of Lipid-Regulating Drugs. Med Letter 2001: 121-130.
6. Oregon Health Resources Commission. HMG-Co A Reductase Inhibitors (Statins), Subcommittee Report. June 2002.